surface exposure and a gene encoding a transactivating protein of human immunodeficiency virus type 1 (HIV-1), wherein said bacterial host can induce anti-HIV-1 immune responses.

REMARKS

Amendment

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

The 35 U.S.C. §112 Rejection

Claims 6-10 were rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The rejection is respectfully traversed.

Claims 6-10 are drawn to a method of initiating immune responses specific for HIV-1 antigens in an animal by the attenuated bacterial host disclosed herein. Applicants submit that the specification has provided detailed disclosure on the induction of anti-HIV-1 immune responses by the attenuated bacterial host (Examples 7-9).

The Examiner stated that "[he] is assuming that the purpose of the immune response is to generate a protective or therapeutic response in the "individual in need of such treatment". Presumably, this is a human being who is infected with HIV-1...." However, claim 6 does not recite or claim treatment in individual; rather claim 6 is drawn to a method of initiating immune responses specific for HIV-1 antigens in an animal.

The Examiner also raised a number of issues with regard to the problems of anti-HIV immune responses in human and the failure of anti-HIV vaccine in clinical trials. However, claims 6-10 are not drawn to anti-HIV immune responses in human or anti-HIV vaccine in human. Applicants submit that the claimed method of initiating immune responses specific for HIV-1 antigens in an animal is fully supported and enabled in the specification (Examples 7-9). Accordingly, Applicants respectfully request that the rejection of claims 6-10 under 35 U.S.C. §112, first paragraph, be withdrawn.

The 35 USC §102 Rejections

Claims 1, 2 and 11 were rejected under 35 U.S.C. §102(b) as anticipated by **Hone** et al. This rejection is respectfully traversed.

Hone disclosed attenuated *Salmonella* vaccine vector containing expression vector encoding HIV-1 gp120 fusion protein. In contrast, the present invention is drawn to a *Salmonella* host containing expression vector encoding HIV-1 transactivating protein. **Hone** did not teach or suggest making an attenuated *Salmonella* host containing expression vector encoding HIV-1 transactivating protein. Since **Hone** does not teach or suggest each and every aspect of the instant invention, **Hone** does not anticipate claims 1, 2 and 11 of the instant application. Accordingly, Applicants respectfully request that the rejection of claims 1, 2 and 11 under 35 U.S.C. §102(b) be withdrawn.

The 35 USC §103(a) Rejections

Claim 5 is rejected under 35 U.S.C. §103(a) as being unpatentable over **Hone** et al. This rejection is respectfully traversed.

Hone disclosed attenuated *Salmonella* vaccine vector containing expression vector encoding HIV-1 gp120 fusion protein. **Hone** did not teach or suggest making an attenuated *Salmonella* host containing expression vector encoding HIV-1 transactivating protein as claimed herein. Accordingly, Applicants respectfully request that the rejection of claim 5 under 35 U.S.C. §103(a) be withdrawn.

Claim 3 is rejected under 35 U.S.C. §103(a) as being unpatentable over **Hone** et al. in view of **Goff** and **Tanese** or **Thimmig** and **McHenry**. Since claim 3 has been cancelled, the rejection is moot.

Claims 1-3, 5 and 11 were rejected under 35 U.S.C. §103(a) as being unpatentable over **Brey** et al. in view of **Zenno** and **Inouye** and **Goff** and **Tanese** or **Thimmig** and **McHenry**. This rejection is respectfully traversed.

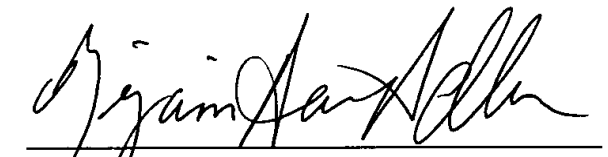
Brey et al. disclosed attenuated strain of bacteria that express malarial antigens. **Zenno** taught the production of large quantities of secretory protein using expression cassettes that contain *E. coli* signal sequence. **Goff** or **Thimmig** disclosed *E. coli* expression vectors encoding HIV-1 reverse transcriptase. In contrast, claim 1 of the present invention is drawn to an attenuated bacterial host comprising a recombinant plasmid encoding a transactivating protein of HIV-1. Applicants submit that the cited references did not teach or suggest an attenuated bacterial host expressing HIV-1 transactivating protein. Hence, the combined teaching of these references does not provide a person having ordinary skill in this art with the requisite expectation of successfully producing Applicants' claimed methods. The

invention as a whole is not *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Accordingly, Applicants respectfully request that the rejection of claims 1-3, 5 and 11 under 35 U.S.C. §103(a) be withdrawn.

This is intended to be a complete response to the Final Office Action mailed March 9, 2001. Applicants submit that the pending claims are now in condition for allowance. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

Date: Sept 10, 2001



Benjamin Aaron Adler, Ph.D., J.D.
Registration No. 35,423
Counsel for Applicant

ADLER & ASSOCIATES
8011 Candle Lane
Houston, Texas 77071
(713) 270-5391